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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,364	10/22/2003	Aaron H. Shovers	S006-P03038US	9385

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,364	SHOVERS ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10/22/03 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Independent claims 1, 16, and 24 (and their respective dependent claims) refer to a method of monitoring the condition of an animal that includes the step of selecting a monitoring material for introduction into the animal. A wide variety of potential conditions to be monitored were mentioned in the specification including immunity, the ability to produce antibodies, general or specific disorders of the immune system, or the general condition of the animal in paragraph 22, lines 2 – 4. Conditions such as hormone levels, temperature, and blood pressure were also discussed in paragraph 25, line 2. The condition may include detection of exposure to radiation, temperature, lack of sleep, or mental stress; the condition may be presence or levels of certain proteins, amino acids, microbes, toxins, drugs, minerals, vitamins, insulin, hormones, etc., as described in paragraph 25, lines 3 – 7. The monitoring material was recited as "certain chemicals, a naturally weak organism or attenuated virus, fungus, bacteria; or other organic and inorganic irritants" in paragraph 26, lines 2-4 of the specification. The

claims to do not specify a particular monitoring material. Claim 9 states that the monitoring material may be selected from the group consisting of organic materials and inorganic materials, and claim 18 repeats claim 9 with the addition of living tissues. Because of the multitude of organic materials, inorganic materials, and living tissues potentially available to the skilled artisan, a more detailed description of what is being claimed is necessary to show possession of the invention. For example, a *specific material* that can be used to monitor a *specific condition* should be described, as well as how the monitoring takes place. In sum, the specification does not provide any description of the specifics of the steps required to practice the very broad and generic monitoring method as claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "easily monitored" in claim 8 is a relative term which renders the claim indefinite. The term "easily monitored" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hence, Applicant is respectfully requested to clarify the claim in order that one may readily ascertain what is being claimed.

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the method of implanting" in the first two lines of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 10 is dependent upon claim 1, which does not refer to a "method of implanting", although it does refer to "introducing the monitoring material into the animal at selected sites."

6. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "dangerous" and "especially conspicuous" in claim 25 are relative terms which render the claim indefinite. The terms "dangerous" and "especially conspicuous" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hence, Applicant is respectfully requested to clarify the claim in order that one may readily ascertain what is being claimed.

7. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites the limitation that "the selected site has a fourth appearance which is especially conspicuous" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 25 is dependent upon claim 18, which does not refer to an "appearance" (first through third or

otherwise). Perhaps Applicant intended for claim 25 to be dependent upon claim 24 rather than claim 18. Claim 24 refers to the first through the third "appearances that appear to be a small change from the first appearance."

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 7 – 10, 12, 13, 16 – 19, 21, 22, and 24 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Medveczky (U. S. Patent 3,452,135; issued 24 June 1969).

Medveczky teaches a process for percutaneous introduction of skin test diagnostic agents for revealing hypersensitivity, or allergy, in human or animal subjects (see abstract). Regarding claims 1 and 16, the selected monitoring material is a biologically active diagnostic agent capable of inducing allergy selected from bacteria, fungi, viruses, or antigenic protein substances along with at least 10% carbamide or thiocarbamide and at least 15% of a lipophilic adjuvant (see claim 1). The site selected for introducing the monitoring material is the forearm (see column 3, line 4). The material is introduced by rubbing a dispersion of the material on the site, which may result in a visually observable "lichenoid knot" at the site of rubbing useful for the diagnosis of tuberculosis, for example (see column 3, line 6). The status of the

individual is visually ascertained by the presence or absence of such a knot (column 3, lines 23-24). Regarding claim 2, the material is localized to the site of introduction, as the knot occurs at the site of rubbing (column 3, line 6). Regarding claims 7, 17, and 26, the selected condition that Medveczky teaches is allergy (see abstract). Regarding claim 8, the site is relatively easily monitored because the knots can generally be touched and seen for 7-8 days (see column 3, lines 9-10). In regard to claims 9 and 18, the monitoring material named previously is considered to be organic material. Regarding claims 10 and 19, the material is implanted by absorption, whereby the carbamide or thiocarbamide and lipophilic agents in the claimed invention are useful for aiding the penetration of the allergen into the skin (column 1, lines 46 – 70). Regarding claims 12, 13, 21, and 22 the site of introducing the material (the forearm of a human) would be considered to be relatively hairless and free of blemish. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Medveczky. Claims 24 and 25 recite periodically observing the site wherein if the status of the condition is normal, then the selected site has a first appearance and wherein if the status of the condition changes, then the selected site has additional appearances. Medveczky addresses these limitations in teaching that on persons not infected by tuberculosis, no specific reaction is observed (i.e. the first appearance indicates that the individual is normal). A visible reaction to the monitoring material indicates a positive tuberculosis diagnosis, and Medveczky also teaches that the development in time of the reaction to an allergy can be monitored (column 3, lines 70-74).

10. Claims 1, 2, 4, 5, 7 – 10, 12, 13, 15 – 19, 21, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender (U. S. Patent 2,151,495; issued 21 March 1939).

Bender teaches a disclosing solution containing Guinea Green B and/or Rose Bengal which is applied to the teeth with a small brush, that renders visible bacterial plaques on the teeth by forming temporary stains on plaque on the teeth (see paragraph 1, lines 1 – 9, paragraph 8 lines 51 – 55, and claims 1 – 7. Regarding claims 1, 4, 5, 7, 16, 17, and 26, the condition that is monitored is plaque on the teeth that can lead to tooth decay (paragraph 1, lines 1 – 9). The monitoring material is a disclosing solution containing Guinea Green B and/or Rose Bengal (claims 1 – 3). The method of introducing the monitoring material is by applying the solution to the teeth with a small brush or wad of cotton. The site for introducing the material is inside the mouth, and more specifically is on the teeth (paragraph 8, lines 51 – 55). As a result of introducing the material, a visually ascertainable indication of the status of the condition appears at the site of introduction of the material because the parts of the teeth that are stained are the affected parts (paragraph 7, lines 1 – 3). Thus, observing the indication allows one to visually ascertain the status of the condition. Regarding claim 2, the monitoring material is localized, because it remains on the teeth. Regarding claim 8, the site is considered to be easily monitored because the site can be viewed by an individual opening the mouth. Regarding claims 9 and 18, the aforementioned monitoring material is considered to be organic material. Regarding claim 10 and 19, the method of

implanting is absorption. Regarding claims 12, 13, 21, and 22, the tooth is generally considered to be relatively hairless and blemish-free. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Bender.

11. Claims 1, 4, 6 – 9, 12 – 18, 21, 22, 23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkett (U. S. Patent 6,830,743; issued 14 December 2004, which claims priority to PCT Publication WO 01/54696; published 2 August, 2001).

Burkett teaches a stain compound that is useful for the identification of dysplastic (i.e. abnormal) epithelial tissue. Regarding claims 1, 4, 6, 7, 16, 17, and 26, the condition that is monitored is dysplastic epithelial tissue, which can be easily missed by routine visual examination by clinicians, and may be cancerous or precancerous (column 1, lines 1-50). The monitoring material is a biological stain having a structural formula depicted in claims 1 – 4. The method of introducing the monitoring material is by rinsing the mouth and gargling with the test solution for one minute (column 13, lines 32-33). The site of introduction of the monitoring material is inside the mouth, specifically epithelial tissue (i.e. the cheek). As a result of introducing the material, a visually ascertainable indication of the status of the condition appears at the site of introduction of the material because early erythroplastic lesions are stained blue (column 13, line 52). Thus, observing the indication allows one to visually ascertain the status of the condition. Regarding claim 8, the site is considered to be easily monitored

because the site can be viewed by an individual opening the mouth. Regarding claims 9 and 18, the aforementioned monitoring material is considered to be organic material. Regarding claims 12, 13, 21, and 22, the cheek is generally considered to be relatively hairless and blemish-free. Regarding claims 14 and 23, the site is prepared for introduction of the monitoring material by rinsing with a pre-rinse solution for approximately 20 seconds (column 13, lines 25-27). Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Burkett.

12. Claims 1, 3, 7 – 9, 12, 13, 15 – 19, 21, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeiler (PCT Publication WO 02/39963 A1; published 23 May, 2002).

Zeiler teaches a composition comprising a copper salt useful for detecting fungal infection in a human nail. Regarding claims 1, 3, 7, 16, 17, and 26, the condition that is monitored is the presence of fungal infection in a human nail. The monitoring material is a composition comprising a copper salt, preferably copper (II) sulfate (page 4, lines 1 – 10). One method of introducing the monitoring material is by applying a nail polish or other composition (page 4, lines11 – 13). The site of introduction of the monitoring material is the nail tissue, which can be interpreted to include under the nail. As a result of introducing the material, a visually ascertainable indication of the status of the condition appears at the site of introduction of the material because the monitoring material stains fungal infected nail tissue (page 4, lines 24-26). Thus, observing the

indication allows one to visually ascertain the status of the condition. Regarding claim 8, the site is considered to be easily monitored because the site can be observed by simply viewing the nail tissue of an individual. Regarding claims 9 and 18, the aforementioned monitoring material is considered to be inorganic material. Regarding claims 12, 13, 21, and 22, the nail is generally considered to be relatively hairless and blemish-free. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Zeiler.

13. Claims 1, 7 – 13, 16 – 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns *et al.* (U.S. Patent 6,440,388 B1; issued 27 August, 2002).

Burns *et al.* teach a solution or suspension that may be in the form of a shampoo, cream, lotion, or detergent that is useful for the visual detection of chitin-containing organisms present in body hair, on skin, on clothing, or on fur (see abstract). Regarding claims 1, 7, 16, 17, and 26, the condition that is monitored is presence of chitin-containing organisms (i.e. lice, nits, mites, ticks, and fungal infections) (column 2, lines 6 – 8). The monitoring material is a dye such as calcofluor white, uvitex 3B, Rylux BA that fluoresce in ultraviolet or visible light (column 3, lines 8 – 32). The method of introducing the monitoring material is by spreading on the site to be monitored (column 5, line 11). The site of introduction of the monitoring material is body hair, skin, clothing, or fur of an animal (column 2, lines 27 – 28). As a result of introducing the material, a visually ascertainable indication of the status of the condition appears at the site of introduction of the material because the area affected by the monitoring material

fluoresces upon exposure to UV light (column 5, lines 22 – 24). Thus, observing the indication allows one to visually ascertain the status of the condition (i.e., the presence of chitin-containing organisms). Regarding claim 8, the site is considered to be easily monitored because the site can be observed by simply viewing the skin or other area after UV irradiation. Regarding claims 9 and 18, the aforementioned monitoring material is considered to be organic material. Regarding claims 10 and 19, the method of implanting the monitoring material is absorption (i.e. into the skin). In regard to claims 11 and 20, the monitoring material may be suspended in a lotion and the material introduced to an individual's skin (see column 3, lines 7-20 and claims 1 and 3). Regarding claims 12, 13, 21, and 22, the skin is generally considered to be relatively hairless and blemish-free. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Burns *et al.*

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER